



CLIA Perspective HIV Rapid Test Consultation

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Background Waived Lab Studies

- **Intent of CLIA:** To ensure accurate & reliable laboratory testing & to maintain access.
- 175,000 laboratories enrolled in CLIA.
 - 54% do only waived tests.
 - 23% do PPMP and/or waived tests.
 - 23% do moderate and/or high complexity tests.
- CMS supports *quality* point of care & rapid testing.

Background Continued

- **CLIA Law**—Waived tests employ simple & accurate methodologies & have insignificant risk of erroneous result or patient harm if performed incorrectly.
- Waived tests have no routine oversight under CLIA & can be performed by anyone, anywhere.
- **CLIA regulations**—Follow manufacturer's instructions—**ONLY** requirement.

Waived Lab Study Findings

- Eleven states conducted studies of over 900 waived laboratories.
- 50% of labs had quality testing problems.
 - Not following manufacturer's instructions.
 - Testing personnel not trained.
 - Not performing Quality Control.
- Labs in states with lab licensure programs performed **10X** better!



OIG STUDY FINDINGS

- Inability to identify incorrect results,
- Untrained staff,
- Lack of testing quality control,
- Poor equipment & reagent storage,
- Poor record keeping.



Waived Lab Study Summary

- 48% of waived laboratories have quality testing problems.
- Lab staff, including M.D.'s & R.N.'s, were not following manufacturer's instructions.
- Laboratories located in states with lab regulations have many fewer problems.
- All labs visited want to produce quality results.

Waived Lab Study Summary

Continued

- Significant findings in combination have serious implications for patients; i.e., incorrect results:
 - Not following manufacturer's instructions;
 - No QC **AND**
 - Lack of testing personnel training.
- Lab experts agree that ANY incorrect test result has the potential risk of harm to a patient.

Moderate Complexity vs Waived

- Application process *identical* for Moderate Complexity & Waived Certificates.
- Simple 4 pg. application on CMS web site @ www.cms.hhs.gov/clia/ or state Dept. of Health.
 - Complete form.
 - Return to state Health Dept. CLIA section.
 - Pay fee to CMS.
 - Receive Registration Certificate, if moderate complexity or
 - Certificate of Waiver, if waived.

Moderate Complexity vs Waived

❑ Waived or Moderate Certificates:

- One certificate per site or

❑ Options on application.:

- Limited public health for multiple sites:
 - » Federal, state, local p.h. or not-for-profit.
 - » Combination 15 waived & moderate tests.
- Mobile lab or temporary testing sites:
 - » Multiple sites; any type or no. of tests.
- Hospital/university labs on one campus:
 - » Contiguous bldgs.; one director.



Moderate Complexity vs Waived

- Moderate Complexity Quality Standards:
 - Personnel Qualifications
 - » Director -- B.S. in science w/ experience.
 - » Testing personnel--H.S. w/ training.
 - Quality Control (Q.C.)
 - » Manufacturers require QC for **BOTH** waived & moderate tests.
 - » Use manufacturer's instructions, text books for procedure manual.

Moderate Complexity vs Waived

- Moderate Complexity Quality Standards:
 - Proficiency testing (P.T.)
 - » Educational value to laboratory published.
 - » One enrollment per certificate decreases costs/burden for labs using cert. options.
 - Patient Test Management = record keeping system
 - » Patient identification & confidentiality.
 - » Use patient chart, computer;
 - No required forms.

Moderate Complexity vs Waived

- Moderate Complexity Quality Standards
 - Quality Assurance (Q.A.)
 - » Encompasses all quality standards in CQI;
 - » Includes communication, problem resolution;
 - » Compare lab data to patient information;
 - » Incorporates many things labs already do!

Moderate Complexity vs Waived

■ Moderate Complexity Oversight--

- Biennial onsite surveys.
- Choice of accred. org. (peers) or CMS (state surveyors).
- Survey fees based on annual test volume.
\$\$ Low volume bargains available.\$\$
- Educational w/ QA focus.
- Good performers rewarded w/ self-assessment on alternate cycles.

Summary Moderate Complexity

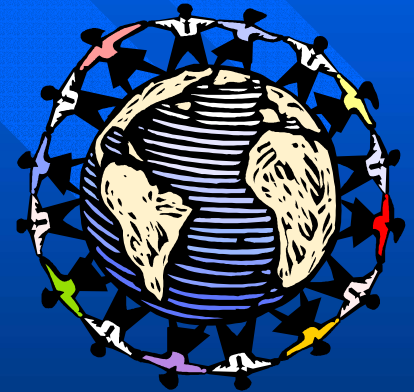
- Minimum standards safeguard quality & facilitate access.
- Low cost & burden to labs; uses existing systems.
- Technical assistance available from CMS, states, local labs, accred. orgs.
- Accredited labs doing waived tests meet moderate complexity standards easily now.
- 10 yrs. CLIA data show no loss of access & better quality for 40,000 labs, incl. 20,000 POLs.
- NY study of HIV-pos. patients reflects increased access & treatment in regulated environment.

Committee Recommendations

- BPAC & CLIAC recommended that **Rapid HIV is not a candidate for CLIA waiver.**
 - Lab experts, lab prof. orgs. & others don't support HIV waiver; agree access is critical.
 - They perform the most testing & thereby, have the greatest insight into possible pitfalls.
 - Mod. complexity can provide quality & access.
- Some public health & clinical experts recommend waiver if the test meets waived criteria.
 - HIV/AIDS is a huge public health issue requiring major efforts.
 - Increased access means early diagnosis, treatment.

Final Note

- CMS supports rapid HIV testing.
- CMS has the same concerns as public health officials.
- CMS wants to ensure access.
- CMS will provide technical assistance beyond CLIA; to facilitate access, to ensure quality testing & the entire continuum of HIV testing is successful.



CMS WAIVED STUDIES & MODERATE COMPLEXITY STANDARDS

QUESTIONS???

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